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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,402	05/30/2001	Kevin Morton	NEOMTRX.004A	7475

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EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/21/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,402

Applicant(s)

MORTON, KEVIN

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 and 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS papers 8, 11.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VII, claims 33 – 35 and 40 in Paper No. 10 is acknowledged.

Claims 1 – 32 and 36 – 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter. Claims 33 – 35 and 40 have been considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 33 – 35 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 – 35 and 40 are drawn to a method for screening for breast cancer, however are rendered vague and indefinite because the method appears to recite steps for collecting breast ductal fluid, not steps for screening breast cancer. Moreover, it is unclear how one would practice the claimed method for screening for breast cancer, by merely screening for at least one indicium of a physiological condition (as recited in lines 8 – 9 in claim 33, the only step which positively recites a method for screening for breast cancer).

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The claims are further indefinite because it is unclear what is required by the limitation "physiological condition" because the phrase is not clearly defined by the claim language or specification. For example, can any physiological condition be an indicium for breast cancer? Moreover, it is unclear what physiological condition(s) are required to meet the limitation of the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 33 – 35 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hung et al. (US 6413228).

Applicant claims a method for screening breast cancer in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the duct, removing the carrier fluid through the opening, screening the removed fluid for at least one indicium of a physiological condition. The

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method step of removing the fluid is assisted by applying suction to the duct opening, the screening step comprises screening for cytologically abnormal cells and the indicium comprises a breast disease marker.

Hung teaches methods for collecting breast ductal fluid comprising cellular material and markers (disease markers) to identify breast precancer or cancer in patients (abstract). Hung teaches the method wherein a wash fluid (carrier fluid) is introduced into the breast duct followed by removal via aspiration (or suction) (col.11 line 45 – col.13 line 45). The cellular material is then cytologically screened for cell conditions and other disease markers such as chromosomal abnormalities (col. 12 – 13).

The reference anticipates the claimed subject matter.

6. Claims 33, 35 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Love (US 6221622).

Applicant claims a method for screening breast cancer in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the duct, removing the carrier fluid through the opening, screening the removed fluid for at least one indicium of a physiological condition. The screening step comprises screening for cytologically abnormal cells and the indicium comprises a breast disease marker.

Love teaches methods for obtaining cellular material from breast ducts (abstract) for screening, diagnosing and monitoring disease states, cancer and pre cancerous conditions (col.3 line 5-20). Specifically, the method comprises introducing a wash fluid (carrier fluid) into a

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breast ductal orifice (external opening), collecting (removing) the fluid and screening the material for cellular markers, morphological, histochemical and/or immunohistochemical abnormalities to determine the presence of cancer or pre-cancerous conditions (physiological conditions) (col.3).

The reference anticipates the claimed subject matter.

7. Claims 33 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by "Final Results of Ductal Lavage Study Presented At 23rd Annual San Antonio Breast Cancer Symposium" (Dec. 2000).

Applicant claims a method for screening breast cancer in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the duct, removing the carrier fluid through the opening, screening the removed fluid for at least one indicium of a physiological condition. The screening step comprises screening for cytologically abnormal cells.

"Ductal Lavage" teaches a method for collecting cells from breast ducts wherein the method comprises introducing fluid into the ductal opening, removing the fluid, and screening the fluid for cytologically abnormal cells, atypical cells or suspicious cells that may indicate cancer (see entire reference).

The reference anticipates the claimed subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
October 16, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER